Appln. No.: 10/572,754

Amendment Dated February 26, 2010 Reply to Office Action of December 1, 2009

<u>Amendments to the Claims:</u> This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

- 1. (Currently Amended) Particles for drug delivery by inhalation, comprising <u>carrier</u> particles and particles containing at least one active ingredient which is non-crystalline, wherein the <u>outer surface of the particles is substantially smooth carrier</u> particles are bigger than the particles containing at least one active ingredient and the particles containing at least one active ingredient have outer surfaces which are sufficiently smooth so as to minimize forces of adherence between the carrier particles and the particles containing at least one active ingredient.
- 2. (Currently Amended) Particles according to Claim 1, wherein the particles containing at least one active ingredient further comprising contain a second or more active(s) and/or one or more excipients.
- 3. (Currently Amended) Particles for drug delivery according to Claim 1 or Claim 2, wherein the particles containing at least one active ingredient contain a plurality of non-crystalline active ingredients.
- 4. (Cancelled)
- 5. (Currently Amended) Particles according to Claim 3, wherein the particles containing at least one active ingredient are being substantially spherical.
- 6. (Currently Amended) Particles according to Claim 5, wherein the particles containing at least one active ingredient are being oblate spheroidal.
- 7. (Currently Amended) Particles according to Claim 3, wherein the particles containing at least one active ingredient are being substantially oval.
- 8. (Currently Amended) Particles according to Claim 3, wherein the particles containing at least one active ingredient are being substantially elliptical.
- 9. (Currently Amended) Particles according to any preceding claim $\underline{1}$, having wherein the particles containing at least one active ingredient have a particle size in the range 0.5 μ m.
- 10. (Currently Amended) Particles according to Claim 9, wherein the particle size of

Appln. No.: 10/572,754

Amendment Dated February 26, 2010 Reply to Office Action of December 1, 2009

the particles containing at least one active ingredient is being between 1 µm to 3 µm.

- 11. (Currently Amended) Particles according to Claim 9 when dependent on Claim 7 or Claim 8 1, wherein the particles containing at least one active ingredient are oval or elliptical and wherein the longer axis of an oval or elliptical particle having has a length between 1 μ m to 3 μ m.
- 12. (Currently Amended) Particles according to any preceding Claim claim 1, wherein the particles containing at least one active ingredient are being electrically uncharged.
- 13. (Currently Amended) Particles according to any preceding claim 1, wherein the particles containing at least one active ingredient are provided by a method selected from the group comprising consisting of rapid expansion of supercritical solutions, precipitation from gas saturated solutions, gas anti-solvent systems, aerosol solvent extraction systems and spray drying processes.
- 14. (Currently Amended) Particles according to any preceding claim 1, there being wherein the particles containing at least one active ingredient are comprised of from two to four active ingredients.
- 15. (Currently Amended) Particles according to any preceding claim 1, wherein the particles containing at least one active ingredient further comprise comprising a pharmaceutically acceptable particular excipient or excipients.
- 16. (Currently Amended) Particles according to any preceding claim $\underline{1}$, wherein the active ingredients comprising comprise a β_2 -agonist and a steroid.
- 17. (Currently Amended) Particles according to Claim [[15]] <u>16</u>, comprising wherein the steroid comprises fluticasone-dipropionate and the β_2 -agonist comprises salmeterol xinafoate.
- 18. (Withdrawn) Particles according to any one of Claims 1 to 15, comprising formoterol and budesonide.
- 19. (Currently Amended) Particles for drug delivery according to any of claims 2 to 18 claim 1, the or wherein the particles containing at least one active ingredient further contain one or more excipients with each excipient being soluble in conditions obtaining in the nose, lung(s) or mouth of a human or animal.

TEVE-113US

Appln. No.: 10/572,754

Amendment Dated February 26, 2010 Reply to Office Action of December 1, 2009

- 20. (Withdrawn) An inhalation composition, comprising particles which incorporate at least one active ingredient which is non-crystalline, wherein the particles have an outer surface that is substantially smooth.
- 21. (Withdrawn) A composition according to Claim 20, further comprising a second or more active(s) and/or one or more excipients.
- 22. (Withdrawn) A composition according to Claim 20 or 21, the particles containing a plurality of active ingredients, which active ingredients are non-crystalline.
- 23. (Withdrawn) A composition according to Claims 20 to 22, there being from two to four active ingredients.
- 24. (Withdrawn) A composition according to any of Claims 21 to 23, the particles comprising a pharmaceutically acceptable excipient within the particle.
- 25. (Withdrawn) A composition according to any of Claims 21 to 24, the particles comprising a pharmaceutically acceptable excipient or excipients where a main excipient is in a greater proportion than the active or actives.
- 26. (Withdrawn) A composition according to Claim 25, the main excipient being Mannitol or PVP.
- 27. (Withdrawn) A composition according to any of Claims 21 to 26, comprising one or more additional carrier excipient(s).
- 28. (Withdrawn) A composition according to Claim 27, said excipient(s) comprising a modifier or stabiliser.
- 29. (Withdrawn) A composition according to Claim 27, said excipient(s) comprising a chemical buffer, antioxidant and the like.
- 30. (Withdrawn) A composition according to Claim 27, said excipient(s) comprising a surface modifier or surfactant.
- 31. (Withdrawn) A composition according to any of Claims 20 to 30, the outer surface of the particles being substantially smooth.
- 32. (Withdrawn) A composition according to Claim 31, the particles being substantially

TEVE-113US

Appln. No.: 10/572,754

Amendment Dated February 26, 2010 Reply to Office Action of December 1, 2009

spherical.

- 33. (Withdrawn) A composition according to Claim 32, the particles being oblate spheroidal.
- 34. (Withdrawn) A composition according to Claim 31, the particles being substantially oval.
- 35. (Withdrawn) A composition according to Claim 31, the particles being substantially elliptical.
- 36. (Withdrawn) A composition according to any of Claims 20 to 35, the particles thereof having a particle size in the range $0.5\mu m 5\mu m$.
- 37. (Withdrawn) A composition according to Claim 36, having a particle size of 1μ to 3μ .
- 38. (Withdrawn) A composition according to Claim 37, the particles being electrically uncharged.
- 39. (Withdrawn) A composition according to any of Claims 20 to 38, provided by a method selected from the group comprising rapid expansion of supercritical solutions, precipitation from gas saturated solutions, gas anti-solvent systems, aerosol solvent extraction systems, and a spray drying process.
- 40. (Withdrawn) A composition according to any of claims 20 to 39, comprising fluticasone and salmeterol xinafoate as active ingredients.
- 41. (Withdrawn) A composition according to any of Claims 20 to 39, the particles comprising formaterol and budesonide as active ingredients.
- 42. (Withdrawn) A composition according to any of Claims 29 to 39, the particles containing one or more cannabinoids as an active ingredient.
- 43. (Withdrawn) A composition according to claim 42, the cannabinoid comprising delta-8 or delta-9 tetrahydrocannabinol.
- 44. (Withdrawn) An inhaler device, comprising an inhalation composition according to any of Claims 20 to 43.

Appln. No.: 10/572,754

Amendment Dated February 26, 2010

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- 45. (Withdrawn) A pulmonary nasal inhalation device, comprising an inhalation composition according to any of Claims 20 to 44.
- 46. (Withdrawn) A device according to Claim 44 or Claim 45, the main excipient being non-soluble in the propellant or propellants.
- 47. (New) Particles according to Claim 1, wherein the carrier particles comprise a carrier selected from the group consisting of lactose and mannitol.